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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,923	05/19/2006	Dominique Marechal	065691-0438	5433

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EXAMINER	
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ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,923	MARECHAL ET AL.	
	Examiner	Art Unit	
	HEATHER L. ANDERSON	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-60* is/are pending in the application.

4a) Of the above claim(s) *54-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/07/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 30-53 in the reply filed on 09 November 2007 is acknowledged. Claims 54-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 30-53 are presented for examination on the merits.

Claim Objections

Claims 30, 32, 35-37, 39 and 41 objected to because of the following informalities: the misspelling of *Ginkgo* and the lack of proper binomial nomenclature formatting for *Ginkgo biloba*. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-34 and 37-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites the limitation "the intermediate water-repellant layer" and is dependent on claim 32. There is insufficient antecedent basis for this limitation in the claim. Claim 32 describes this layer as "an optional water-repellent layer," not "intermediate."

Claim 51 recites the limitation "the coating polymers" and is dependent on claim 50. There is insufficient antecedent basis for this limitation in the claim. Claim 50 does not use the term "coating polymers" therein.

Claim 32 is vague and indefinite due to the possible misconstruing of the relationship of the core and the layer containing Ginkgo biloba and the pharmaceutically acceptable excipient. As written, it is unclear whether or not the layer contains the Gingko biloba extract or if the neutral core contains it. It is also unclear whether the pharmaceutically acceptable excipient is with the Gingko biloba extract or the neutral core. In the interest of compact prosecution, the relationship has been assumed to be that the layer contains both the Gingko biloba extract and the pharmaceutically acceptable excipient based on the guidance provided by the specification and further dependent claims. It is recommended that the claim be amended to state "a neutral core coated with a layer, said layer containing..." for clarity.

Claim 49 appears to be improperly dependent on claim 48 and would more appropriately be dependent on claim 46, as claim 46 refers to "the outer polymeric layer."

Claim 52 also appears to be improperly dependent. Claim 52 depends upon claim 37 but would appear to more appropriately depend upon claim 49; otherwise this claim would essentially be a duplicate of claim 40.

All other claims depend directly or indirectly from rejected claims and are therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 30-34 and 37, 38, 40, 42, 44-49 and 52 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Debregeas et al. (US 2004/0081691).

Sustained-release microgranules comprising a neutral core coated by a layer containing *Ginkgo biloba* extract and a pharmaceutically acceptable excipient which is further coated by an outer polymeric layer is claimed.

Debregeas et al. teach granules having a neutral core with a particle size between 200 and 1600 µm coated with a layer containing a plant substance combined with a pharmaceutically acceptable carrier (see, e.g., the abstract and entire document). *Ginkgo biloba* extract is taught as one of three exemplified plant substances (see, e.g., Examples 4 and 5 on page 3, second column). The neutral core can consist of about 80% starch and 20% sucrose (see, e.g., paragraph [0023]). The layer containing the plant substance may contain a binder, such as sucrose, polyvinylpyrrolidone (povidone), and hydroxypropylmethyl-cellulose (a cellulosic polymer) (see, e.g., paragraph [0024]).

Debregeas et al. further teach that the neutral core coated with a layer containing the plant substance may itself be coated with an outer layer so as to modify the microgranules' properties (see, e.g., paragraph [0012]). This includes an outer layer comprising a polymer intended to prolong the release of the plant substance. Under the Detailed Description of the Preferred Embodiments, specific examples of these polymers are listed, such as a copolymer of methacrylic acid (an acrylic polymer) with a plasticizer (see, e.g., [0026]). As all the above characteristics of the microgranules of Debregeas et al. are the same as the instant claims listed above, the dissolution profile of the microgranules would inherently be the same as described in claims 30 and 31.

In the alternative, even if the claimed sustained-release microgranules are not identical to the referenced sustained-release microgranules with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced sustained-release microgranules are likely to inherently possess the same characteristics of the claimed sustained-release microgranules particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed sustained-release microgranules would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' sustained-release microgranules differs and, if so, to what extent, from those disclosed by the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Claim Rejections - 35 USC § 103

Claims 30-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debregeas et al. (US 2004/0081691) in view of O'Hara et al. (Archives of Family Medicine).

Debregeas et al. beneficially teach granules having a neutral core with a particle size between 200 and 1600 µm coated with a layer containing a plant substance combined with a pharmaceutically acceptable carrier (see, e.g., the abstract and entire document). *Ginkgo biloba* extract is beneficially taught as one of three exemplified plant substances (see, e.g., Examples 4 and 5 on page 3, second column). The neutral core can consist of about 80% starch and 20% sucrose (see, e.g., paragraph [0023]). The layer containing the plant substance may contain a binder, such as sucrose, polyvinylpyrrolidone (povidone), and hydroxypropylmethyl-cellulose (a cellulosic polymer) (see, e.g., paragraph [0024]). Debregeas et al. further beneficially teach that the neutral core coated with a layer containing the plant substance may itself be coated with an outer layer so as to modify the microgranules' properties (see, e.g., paragraph

[0012]). This includes an outer layer comprising a polymer intended to prolong the release of the plant substance. Under the Detailed Description of the Preferred Embodiments, specific examples of these polymers are listed, such as a copolymer of methacrylic acid (an acrylic polymer) with a plasticizer (see, e.g., [0026]). The weight of the extract in relation to the weight of the granule is preferably between 35-55%, which leaves 45-65% for the remaining ingredients, such as binders and plasticizers (see, e.g., paragraph [0047]. As all the above characteristics of the microgranules of Debregeas et al. are the same as the instant claims listed above, the dissolution profile of the microgranules would intrinsically be the same as described in claims 30 and 31.

Debregeas et al. does not teach the percentage of flavonoid or terpenes in the *Ginkgo biloba* extract.

O'Hara et al. beneficially teach that patients using *Ginkgo biloba* extract should use the extract Egb 761, which has been studied in all reported clinical trials (see, e.g., third column, first paragraph). This extract has been standardized to 24% flavonoid glycosides and 6% terpenoids (terpenes).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the standardized extract Egb 761 as the *Ginkgo biloba* extract component of the microgranules of Debregeas et al., as suggested by O'Hara et al., and produce the instant invention. One of ordinary skill in the art would have been motivated to do this because this extract has been standardized and thoroughly studied in clinical trials. The adjustment of particular conventional working conditions (e.g., determining suitable weight percentages for each component of the

microgranules and/or using a particular type of plasticizer) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather L. Anderson whose telephone number is (571)270-3051. The examiner can normally be reached on Monday-Thursday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HLA

CHRISTOPHER R. TATE
PRIMARY EXAMINER